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Proposed Re-evaluation Decision

Propylene Glycol

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Overview

What Is the Proposed Re-evaluation Decision?

After a re-evaluation of propylene glycol, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of the pest control product containing the active ingredient propylene glycol for sale and use in Canada.

An evaluation of available scientific information found that the product containing propylene glycol does not present unacceptable risk to human health or the environment when used according to the label directions. No additional data are being requested at this time.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for propylene glycol and presents the reasons for the proposed re-evaluation decision.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of propylene glycol.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks as well as value of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Propylene glycol, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in a 2006 RED, the USEPA concluded that propylene glycol was eligible for reregistration. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation section of this consultation document.

What Is Propylene Glycol?

Propylene glycol is a hard surface sanitiser used to control germs on household surfaces. Homeowners can apply propylene glycol by spraying the ready-to-use solution at the target area and then wiping the sprayed area.

Health Considerations

Can Approved Uses of Propylene Glycol Affect Human Health?

Propylene glycol is unlikely to affect your health when used according to the label directions.

People could be exposed to propylene glycol by applying it on surfaces or if they are in contact with treated surfaces. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that propylene glycol was unlikely to affect human health. These conclusions apply to the Canadian situation.

Environmental Considerations

What Happens When Propylene Glycol Is Introduced Into the Environment?

Propylene glycol is unlikely to affect non-target organisms when used according to the label directions.

The USEPA concluded that the reregistration of propylene glycol was acceptable. These conclusions apply to the Canadian situation.

Next Steps

Before making a final re-evaluation decision on propylene glycol, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] document that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Propylene glycol is a hard surface sanitiser. Following the re-evaluation announcement for propylene glycol, the registrant in Canada indicated that they intended to provide continued support for all uses included on the label of the domestic end-use product in Canada.

The PMRA used recent assessments of propylene glycol from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) for propylene glycol, dated September 2006, as well as other information on the regulatory status of propylene glycol in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient

Common name	Propylene glycol
Function	Sanitiser
Chemical Family	None
Chemical name	1,2-Propanediol or 1,2-hydroxypropane
International Union of Pure and Applied Chemistry (IUPAC)	Propane-1,2-diol
CAS Registry Number	57-55-6
Molecular Formula	$C_3H_8O_2$
Structural Formula	$OH\text{-}CH_2\text{-}CH(OH)\text{-}CH_3$
Molecular Weight	76

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	Result	Interpretation
Vapour pressure	0.04–0.08 mm Hg	High volatility
Henry's law constant	1.31×10^{-10} atm m^3/mole (at 25°C)	Non-volatile from a water surface or moist soil
Solubility in water	Very soluble in water. Potential for leaching.	

Property	Result	Interpretation
n-Octanol–water partition coefficient	log K_{ow} -0.92	Bioaccumulation is unlikely

2.3 Comparison of Use Patterns in Canada and the United States

Propylene glycol is a hard surface sanitiser registered in Canada to control household germs. It is used on glass surfaces, household surfaces, countertops, stovetops, sinks, refrigerators, microwaves ovens, appliances, stainless steel, chrome fixtures, glazed ceramic tile, formica, porcelain, mirrors, enamel. The end-use product is formulated as a ready-to-use solution.

The American and Canadian use patterns were compared. The formulation type, use sites, application methods associated with the Canadian end-use product are also registered in the United States. Based on this comparison of use patterns, it was concluded that the USEPA RED for propylene glycol is an adequate basis for the re-evaluation of uses of propylene glycol in Canada.

All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of propylene glycol. Appendix I lists the product that is registered as of 27 March 2008 under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2006 RED, the USEPA concluded that the end-use products formulated with propylene glycol met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans or the environment if used according to the product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed the effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure could occur while homeowners apply propylene glycol on surfaces or subsequently if they are in contact with treated surfaces. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

Based on a review of the toxicological database, the USEPA concluded that there are no endpoints of concern for oral, dermal or inhalation exposure to propylene glycol based on the low toxicity observed in studies near or above testing limit doses. Based on this, the USEPA did

not conduct any quantitative human health risk assessments and concluded that exposure does not present a human health risk of concern.

Use of propylene glycol as a domestic sanitiser formulated as the "ready-to use spray solution" registered in Canada is also part of the American use pattern, and the conclusions derived in the RED are considered applicable to the Canadian end-use product.

3.2 Environment

The USEPA concluded that adverse effects to non-target organisms are not anticipated from the indoor use of propylene glycol due to the low likelihood of exposure. The low toxicity of propylene glycol to fish and aquatic invertebrates found in the data obtained from the published literature and the low mammalian toxicity (discussed in Section 3.1) further support the unlikelihood of adverse effects to non-target organisms.

These conclusions are considered applicable to the Canadian propylene glycol end-use product.

3.2.1 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal Toxic Substances Management Policy, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal Toxic Substances Management Policy and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of propylene glycol. The PMRA has reached the following conclusions.

Propylene glycol is not bioaccumulative. The *n*-octanol–water partition coefficient (log K_{ow}) is -0.92 , which is below the TSMP Track 1 cut-off criterion of ≥ 5.0. Propylene glycol does not meet all Track 1 criteria; thus, it is not a candidate for Track 1 classification.

4.0 Proposed Re-evaluation Decision

The PMRA has determined that propylene glycol is acceptable for continued registration. No additional data are being requested.

5.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for propylene glycol is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

a.i.	active ingredient
CAS	Chemical Abstracts Service
IUPAC	International Union of Pure and Applied Chemistry
K_{ow}	*n*-octanol–water partition coefficient
PCPA	*Pest Control Products Act*
PMRA	Pest Management Regulatory Agency
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Registered Products Containing Propylene Glycol as of 27 March 2008

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
25089	Domestic	S.C. Johnson and Son Ltd.	Windex Antibacterial Glass and Surface Cleaner	Ready-to-use solution	Propylene glycol 0.25% Isopropyl alcohol 3.5%